

TAKHZYRO (lanadelumab-flyo)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 2 years of age and older

All other indications are considered experimental/investigational and are not a covered benefit.

III. CRITERIA FOR INITIAL APPROVAL

Authorization for 6 months may be granted for prevention of hereditary angioedema attacks in members 2 years of age or older when the following criteria is met:

- A. Medication is prescribed by, or in consultation with allergist/immunologist or a physician who specializes in the management of HAE
- B. Member has documented diagnosis of HAE type I or type II and meets one of the following (1 or 2):
 1. Documentation that the member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following criteria:
 - a. C1 inhibitor (C1-INH) antigenic level is below the lower limit of normal as defined by the laboratory performing the test; OR
 - b. Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); OR
 2. Documentation that the member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
 - a. Member has an F12, angiopoietin-1, plasminogen or kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing, OR
 - b. Member has a family history of angioedema and the member's angioedema was refractory to a trial of high-dose antihistamine therapy (e.g., cetirizine 40mg per day or the equivalent) for at least one month.
- C. Will not be used in combination with Haegarda (C1 esterase inhibitor), Orladeyo (berotralstat), Andembry (garadacimab-gxii), Cinryze (C1 esterase inhibitor) or Dawnzera (donidalorsen),
- D. Member requires long-term prophylactic treatment based on the provider's assessment of the patient's disease activity, quality of life, availability of health care resources, and/or failure to achieve adequate control by appropriate on-demand therapy [i.e., Ekterly (sebetralstat), Kalbitor (ecallantide), Icatibant, Ruconest (C1 esterase inhibitor) or Berinert (C1 esterase inhibitor), etc.]
- E. Other causes of angioedema have been ruled out (e.g., angiotensin-converting enzyme inhibitor [ACE-I] induced an angioedema, angioedema related to an estrogen containing drug, allergic angioedema).

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy when all of the following criteria are met:

- A. Documentation that the member meets all criteria for initial approval.
- B. Documentation that the member has documentation of experiencing a significant reduction in frequency of attacks (e.g., $\geq 50\%$) since starting prophylactic treatment;
- C. Documentation of the number of acute HAE attacks experienced in the previous 6 months while on Takhzyro therapy is provided and dosing regimen being requested is provided:
 - 1. If member experienced no (zero) acute HAE attacks in the previous 6 months the member is eligible for approval of Takhzyro 300mg given every 4 weeks for 6 months; OR
 - 2. If member experienced one or more acute HAE attacks in the previous 6 months the member is eligible for approval of Takhzyro 300mg given every 2 weeks for 6 months.

IV. QUANTITY LIMIT

Takhzyro 150mg/ml or 300mg/2mL: 2 syringes or vials every 28 days

V. REFERENCES

- 1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; February 2025. Accessed October 2025.
- 2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update. *Allergy*. 2018;00:1-22.